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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,222	10/16/2001	Meir S. Sacks	MSS 49400	6524

7590 04/15/2004

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EXAMINER	
PRATS, FRANCISCO CHANDLER	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,222	SACKS ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 3-22-04.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) 4-7,10-12,14,16 and 23-33 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3,8,9,13,15,17-22 and 34-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 22, 2004, has been entered.

Claims 1-36 are pending.

Election/Restrictions

Applicant's election of the group I invention, claims 1-7, 13-18 and 22, directed to compositions comprising uric acid derivatives, in Paper No. 4, filed April 11, 2003, is acknowledged. Applicant's election of the species (a) xanthosine as the uric acid derivative, (b) vitamin C as the additional ingredient, (c) neurodegenerative disease as the disease to be treated, and (d) hypoxanthine as the uric acid precursor, is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-7, 10-12, 14, 16 and 23-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. As discussed immediately above, election was made **without** traverse in Paper No. 4, filed April 11, 2003.

Claims 1-3, 8, 9, 13, 15, 17-22 and 34-36 read on the elected invention of a composition comprising a uric acid derivative which is xanthosine and an additional ingredient which is vitamin C. Claims 1-3, 8, 9, 13, 15, 17-22 and 34-36 are therefore examined on the merits to the extent they read on the elected species.

Claim Rejections - 35 USC § 103

Claims 1-3, 13, 15, 17, 18, 20, 22 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peeters et al (WO 94/00132).

Peeters discloses the treatment of Alzheimer's disease with guanosine and precursors and/or derivatives thereof, including the elected species xanthosine, as well as guanine, inosine, xanthine, hypoxanthine, 5' inosinic acid, and mono-, di- and triphosphates of guanosine. See claims 1-12, and amended claims 1-12, at pages 14-17 of the English language translation

provided herewith. Thus, Peeters discloses pharmaceutical compositions comprising each of those compounds.

As amended the claims now recite that the compositions contain a "daily dosage amount" of from 100 to less than 1,000 mg. Properly construed at its broadest, the recitation "daily dosage amount" is merely a recitation of intended use, and the claims encompass any composition which can be administered at the claimed daily rate of administration.

Peeters does not explicitly disclose the amounts of any dosage forms, although Peeters does disclose that oral dosage forms such as tablets and gelcaps are suitable for the disclosed compositions. See page 11 of the translation. Peeters also discloses that the elected species xanthosine should be administered at dosages of from 20 mg/kg/day to 150 mg/kg/day. See translation at page 11, lines 3 and 4. Assuming a 50 kg person, this dosage would result in an administration of compositions comprising 1 to 7.5 grams per day. The artisan of ordinary skill clearly would have recognized that a suitable method of administering 1 gram of xanthosine, or more, per day would have been by administering in 500 mg oral dosage forms. Official notice is taken of the fact that the determination of suitable dosage regimens for the therapeutic methods in Peeters, including the use of 500 mg dosage forms, was clearly well

within the purview of the artisan of ordinary skill at the time of applicant's invention. Therefore, the claims must be considered obvious under § 103(a), absent some demonstration of an unexpected result coming from the claimed use of dosage forms containing less than 1 gram, or no more than 500 mg of xanthosine.

Claims 1-3, 8, 9, 13, 15, 17-22 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peeters et al (WO 94/00132) in view of Howard et al (GB 2 280 110).

As discussed above, Peeters renders obvious the treatment of Alzheimer's disease using compositions comprising the claimed amounts of guanosine and precursors and/or derivatives thereof, including the elected species xanthosine, as well as guanine, inosine, xanthine, hypoxanthine, 5' inosinic acid, and mono-, di- and triphosphates of guanosine. Peeters differs from the claims in that Peeters does not disclose the inclusion of the elected additional ingredient vitamin C in described compositions.

However, Howard discloses that vitamin C should be included in a regimen of treating Alzheimer's. See claim 5 on page 27, also claim 14 on page 29. Thus, the artisan of ordinary skill,

reasonably expecting the vitamin C of Howard to be beneficial in Peeters' method of treating Alzheimer's, clearly would have been motivated to have included Howard's vitamin C in the therapeutic regimen disclosed by Peeters. A holding of obviousness is clearly required.

Note that it is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Response to Arguments

All of applicant's argument regarding the pending grounds of rejection has been fully considered but is not persuasive of error. Applicant asserts that because the daily dosage range recited in the claims is different than the daily dosage range in Peeters, the claims are not properly rejected over the Peeters reference. However, applicant's argument entirely

ignores the fact that applicant's claims are not directed to methods of treating a disease by administering a specific medicament at a specific daily dosage rate. Rather, applicant's claims are directed to products.

The intended rate of administration does not, and cannot, change the product itself. Thus, despite the recitation in the amended claims regarding a "daily dosage", all that the claims require is that the composition comprises the claim-designated amounts of the therapeutic ingredient. One of ordinary skill preparing orally-administrable compositions according to the Peeters disclosure clearly would have been motivated to have prepared those compositions in dosage forms containing amounts of the ingredients which would have been suitable for oral administration. Such dosage forms clearly encompass the amounts of the uric acid precursors recited in the pending claims, even as amended. Because the intended dosage regimen does not change the product itself, and because Peeters suggests preparing dosage forms containing the claimed amount of uric acid precursors, the holding of obviousness must be maintained.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP